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(54) Tacky, hydrophilic gel dressings and products therefrom

Klebrige saugfähige Wundverbände und daraus erzeugte Produkte

Pansements hydrophiles collants et produits dérivés

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Description

BACKGROUND OF THE INVENTION

This invention relates to the field of poly(N-vinyl lactam)-urethane gels and more particularly to gels which are skin adhesive and absorbent, which are flexible and contour-conforming, and which can be used in dressings for a variety of applications.

It has been known that polyvinylpyrrolidone (PVP) forms complexes with polyurethanes to yield hydrophilic blends or alloys. U.S. Patent No. 4,642,267 decribes hydrophilic polymer blends of polyurethane and hydrophilic poly(N-vinyl lactam) prepared in solvent solution to provide slippery coatings when wet and which are water insoluble to some extent once cured by drying. In contrast to the slippery coatings described in U.S. Patent No. 4,642,267, the dressings of the present invention are tacky gels.

European Patent Application 107,376 describes tacky PVP gels which require the use of ionizing radiation for cross-linking. U.S. Patent No. 4,646,730 describes a PVP/Silver Sulfadiazine hydrogel dressing in which electron beam radiation is required to cross-link the PVP and form a gel. In addition, magnesium trisilicate, hydrogen peroxide and/or polyacrylic acid are added for color stabilization. It is apparent that there would be an advantage in making tacky skin-adhering gels in the absence of expensive equipment and/or processing.

Ring opening of pyrrolidone groups on PVP was described by H.P. Frank, "The Lactam-Amino Acid Equilibria for Ethylpyrrolidone and Polyvinylpyrrolidone", Journal of Polymer Science 12, 565-576 (1954); and A. Conex and G. Smets, "Ring Opening in Lactam Polymers", J. Poly. Chem. 13, 221-229 (1955). The concept of ring opened pyrrolidone groups is made use of in this invention to unexpectedly attain absorbent and tacky gels.

It is therefore an object of the invention to provide tacky gels having a hydrophilic property.

It is a further object to produce tacky gels without a need for expensive equipment and/or processing.

It is another object to provide tacky gels of poly(N-vinyl lactam) and urethane which can be used in a variety of skin adhesive products.

SUMMARY OF THE INVENTION

Accordingly, there is provided a dressing comprising a stable, tacky hydrophilic gel which comprises a blend of polyurethane or polyurethanes and a poly(N-vinyl lactam) with or without a plasticizer, the poly(N-vinyl lactam) having a K value of at least 60 and mole equivalents of acid groups of at least 1.4. The dressing may also include a substrate which is preferably a polymer film, such as a polyurethane or a silicone-polytetrafluoroethylene film, a collagen film, or a woven or non-woven fabric which may be stretchable. The polymer film may also include an additional skin adhesive which may be applied, for example, around the edges on the side to be applied to skin.

The poly(N-vinyl lactam) is preferably a polyvinylpyrrolidone having mole equivalents of acid groups of at least 2.

The gel dressing is prepared by mixing aqueous poly(N-vinyl lactam) solution and polyurethane in aqueous dispersion at a poly(N-vinyl lactam/polyurethane ratio of from 0.5/1 to 8/1, preferably from 0.75/1 to 4/1 and a total solids content above about 5 weight percent to form a blend, forming the blend into a dressing and allowing the dressing to cure until a gel dressing is formed.

The gel preferably includes at least one additional ingredient which may be releasable from the gel. Preferably the releasable ingredient is a fragrance or a bio-effecting or body-treating material.

Preferred products for which the dressing may be used are wound and burn dressings, drug delivery systems, antimicrobial interface devices, sports wraps, and cosmetic masks and wraps.

The dressings have the advantage of self-adhesion to the skin but with facile peelability. The gels are stable even in hot water, are capable of absorbing many times their weight in water, and are capable or delivering medicaments externally to the body exactly where desired.

For a better understanding of the present invention, together with other and further objects, reference is made to the following description, and its scope will be pointed out in the appended claims.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

It has been found that poly(N-vinyl lactam) such as polyvinylpyrrolidone (PVP), with a degree of ring opened pyrrolidone groups, forms irreversible hydrophilic gels with certain aqueous dispersed polyurethanes. These gels have a tacky quality so that they can adhere to skin but are peelable. The gels are flexible and transparent or translucent and may be used alone or with various additives. The gels can be used for wound and burn dressings, drug delivery systems, cosmetic face and nail wraps, and other applications where the high heat capacity and heat or cold reservoir/transport capacity of water as part of the hydrophilic gel can be utilized.

Suitable poly(N-vinyl lactams) have a K value of at least 60, preferably at least 70, and most preferably from 80 to 110.

In the invention, poly N-vinyl lactams containing above certain levels of ring opened pyrrolidone groups, when mixed with certain aqueous dispersed urethanes, form gels which are tacky. The term tacky is intended to mean having the property of being sticky to the touch or adhesive to a degree that the gel is capable of sticking to the skin while being easily removable when removal is desired.

The term poly(N-vinyl lactam) as used herein shall be understood to include homopolymers, copolymers

and terpolymers of N-vinyl lactams such as N-vinylpyrrolidone, N-vinylbutyrolactam, N-vinylcaprolactam, and the like, as well as the foregoing prepared with minor amounts, for example, up to 20 weight percent, of one or a mixture of other vinyl monomers copolymerizable with the N-vinyl lactams. Copolymers or terpolymers of poly(N-vinyl-lactam) may comprise N-vinyl-lactam monomers such as vinylpyrrolidone copolymerized with monomers containing a vinyl functional group such as acrylates, hydroxyalkylacrylates, methacrylates, acrylic acid or methacrylic acid, and acrylamides. Of the poly(N-vinyl lactam) homopolymers, the polyvinylpyrrolidone (PVP) homopolymers are preferred. Of the poly(N-vinyl lactam) copolymers, vinyl pyrrolidone acrylamide copolymers are preferred. A suitable poly(N-vinyl lactam) terpolymer is vinylpyrrolidone, vinylcaprolactam, dimethylaminoethyl methacrylate. A variety of polyvinylpyrrolidones are commercially available. It is important, however, for the poly(N-vinyl lactam) to contain a degree of ring-opened lactam groups.

A lactam may be considered to be a cyclic amide produced from an amino acid through the elimination of a molecule of water from the -COOH and -NH_2 groups. A lactam, therefore, contains a -NH-CO- group in a ring. An N-vinyl lactam has a vinyl group at the ring nitrogen and the monomer can be polymerized through the vinyl group. In a ring-opened poly(N-vinyl lactam), the vinyl backbone may be considered to remain essentially intact, but some lactam rings are opened to make available -COOH groups. The availability of these -COOH groups may be measured through base titration to determine the mole equivalents of base per mole of acid groups in a specific poly(N-vinyl lactam). Because the polymer backbone remains essentially intact, different poly(N-vinyl lactams) having the same molecular weight or K-value may have different levels of ring openings. The poly(N-vinyl lactams) useful in forming the gels in the invention have a mole equivalent/mole of acid groups greater than 1.4, preferably greater than 2.0. In the absence of opened lactam rings, the gel does not form. The poly(N-vinyl lactams) are preferably of relatively high molecular weight as indicated by a K value above 60.

Ring opening in poly(N-vinyl lactams) may be effected by heating a solution of the poly(N-vinyl lactam) at a temperature of from about 50°C to about 120°C, with from about 60°C to about 100°C preferred, at pressure from about 15 psi to about 150 psi for from about one half hour to about 10 days, with from about one hour to about 24 hours preferred. The solvent for the solution is preferably aqueous and may include a small amount of a weak base such as dilute ammonium hydroxide or dilute sodium hydroxide to result in a solution which is slightly basic, e.g. having a pH of about 7-9, with about 7-8 or 7-8.5 preferred. If time saving is an important consideration as in commercial operations, ring opening may be carried out, for example, for shorter periods of time in a reactor under conditions of high temperature and pressure, e.g. 200°C at 50 psi.

To form the gel, the poly(N-vinyl lactam) is mixed or blended with polyurethane. The urethane portion of the blend is based, for example, on ethoxylates of dimethylol propionic acid reacted with either aromatic isocyanates or aliphatic isocyanate such as toluene diisocyanate (TDI), methylene di-p-phenylene isocyanate (MDI) (diphenylmethane-4,4'-diisocyanate), hexamethylene diisocyanate, or dicyclohexylene diisocyanate, to form a prepolymer, reacted with chain extender and then dispersed in water to which triethylamine is added to partially neutralize the acid function. Urethane resins are commercially available, for example, NeoRez R-940 (Imperial Chemical Industries, Ltd.) and Sancure 847 (Sanncore Industries, Inc.). The polyurethane is preferably in the form of an aqueous dispersion.

The gel may be prepared by dissolving the poly(N-vinyl lactam) such as polyvinylpyrrolidone in aqueous solution, then adding an aqueous dispersed polyurethane with sufficient agitation to attain a homogenous mixture or blend with at least 5% total solids, i.e., at least 5 weight percent total PVP and polyurethane. The solvent used for the gel preparation is preferably substantially aqueous. For example, the gels may be prepared in water or in hydroalcohols such as water/isopropyl alcohol and water/ethanol. The gels form at a ratio of PVP/urethane of from 0.5/1 to 8/1, preferably from 0.75/1 to 4/1, at a total solids of at least 5%. At higher PVP to urethane ratios gels are formed but are weaker and may contain uncomplexed PVP which will leach out in water. At lower solids levels or when the PVP has a K below 60, gels may form but they can be reversed in hot water. The blend may be allowed to cure for a time of from about 15 seconds to about 2 hours. The time and temperature for curing are not critical. For purposes of convenience, ambient temperature may be used but the time can be shortened at elevated temperatures. The term gel is intended to mean viscous or semi-solid and jelly-like.

The preferred gels are stable and therefore irreversible and water insoluble, even in boiling water or alcohol. The gels can be sterilized by radiation or steam sterilization. The gels are hydrophilic and capable of absorbing many times their weight in water or at least twice their weight in water. For practical application as described herein, a gel absorbs, for example, from about 25 to about 40 times its dry weight in water. The gel material may be considered to absorb fluid based on the ratio of PVP/urethane. For example, at a ratio of PVP/urethane of 0.75/1 to 1/1, the gel absorbs about 29 times its dry weight (i.e. solids weight) in water; at 3/1, it can absorb about 38 times its dry weight in water.

While the exact nature of the mechanism by which the gel forms is not known, and while it is not intended to be bound by theory, it is believed to be caused by pervasive and tight hydrogen bonds between chains. The presence of the ring-opened pyrrolidones, in some undetermined way, plays an imperative role in achieving this goal.

Glycerine in an amount of from about 5 to about 50 weight percent, preferably from about 10 to about 30

weight percent may be added to the gel preparation to increase tack and pliability after drying. The glycerine is preferably mixed into the PVP solution prior to adding urethane dispersion. Propylene glycol may also be used.

Many different types of additional materials may be incorporated into the gels including organic salts, inorganic salts at low levels, alcohols, amines, polymer latices, fillers, surfactants, pigments, dyes, fragrances and so forth as long as they do not interfere with gel formation. Many of these materials can be releasable from the gel.

The gels of this invention are especially useful as carriers for a wide variety of releasable biologically active substances having curative or therapeutic value for human or non-human animals. Included among the biologically active materials which are suitable for incorporation into the gels of the invention are hypnotics, sedatives, tranquilizers, anti-convulsants, muscle relaxants, analgesics, antipyretic agents, anti-inflammatory agents, local anesthetics, antispasmodics, antiulcer agents, antivirals, antibacterials, antifungals, sympathomimetic agents, cardiovascular agents, antitumor agents, and so forth. A biologically active substance is added in pharmaceutically active amounts.

Particularly preferred as biologically active additives are nitroglycerine, scopalamine, pilocarpine, phenylpropanolamine, and theophyline; also antimicrobials tetracycline, neomycin, oxytetracycline, triclosan, sodium cefazolin, silver sulfadiazine, and also salicylates such as methylsalicylate and salicylic acid, nicotinates such as methyl nictoninate, capsicum and benzocaine. When the gel is to be used, for example, for cosmetic treatment, hydrating agents such as sodium pyrrolidine carboxylic acid may be added. For a hydrating purpose, however, the large amount of water alone which can be absorbed by the hydrophilic gel serves a hydrating function to the skin.

Water soluble and water insoluble additives such as those described above may be initially mixed with the aqueous solvent before the gel preparation is begun, may be mixed with the aqueous solution of poly(N-vinyl lactam) or mixed with the aqueous dispersed polyurethane during the gel preparation. Water soluble ingredients are preferably mixed in with the PVP prior to admixing with urethane. Many water insoluble ingredients can be mixed with urethane prior to adding to PVP. One can also emulsify water insolubles by adding surfactants to either the PVP or urethane. Alternatively, additives may be similarly mixed into the gel preparation after the poly(N-vinyl lactam) is blended with the polyurethane. Additives may also be applied to the surface of a gel dressing, for example, by spraying, dipping, brushing or rolling.

The gel may be used to make adhesive, absorbent dressings and other products. To obtain the products of the invention, the gel may be provided with at least one substrate or backing and a release liner. To form a dressing, the gel is put on a substrate and covered with a release liner to prevent the gel from sticking to itself thereby forming a sandwich structure with the gel located between a substrate and a release liner. The dressing may also be provided in rolled-up form so that the substrate itself acts as a release liner. In any case, the release liner is removed before the gel is applied to skin. The substrate may fulfill one or several functions including providing reinforcement, providing a gas and liquid barrier, providing a support with gas and liquid permeability, providing protection for the gel and the area of treatment, etc. The substrate may be chosen to supply the desired function(s) and characteristics of the various substrates, e.g. permeability, impermeability, semipermeability, stretchability, etc., are known to those skilled in the art.

The gel may be coated or spread onto a backing or substrate by any means known in the art. The gel can be combined with and adhered to a virtually unlimited variety of substrates or backings including resins, metal foils, woven and non-woven webs of natural and synthetic fibers, etc. A backing which provides gas and liquid barrier properties may be a polymer film such as polyurethane. Desirable composites with the gel may also be made using films of polyvinyl alcohol, polyvinylidene chloride or a silicone-polytetrafluoroethylene interpenetrating polymer membrane or film which is commercially available as Silon (BioMed Sciences, Inc.). When the gel has a barrier substrate of this type, the resulting structure has particular utility as a wound and burn dressing. Moisture is kept in and excess exudate is absorbed to promote healing but bacteria are prevented from entering the wound or burn area, and microbial stasis may be maintained through the incorporation of an anti-microbial agent into the gel to prevent infection. For ease of use, the tacky gel on a backing is covered with a release liner which may be a silicone coated film or polyethylene.

The gel may be coated onto the backing so that the gel occupies all or quart of the backing surface. If the gel occupies part of the backing surface, non-gel coated areas of the backing may be provided with an additional adhesive. A dressing of this type is positioned on the skin so that the additional skin adhesive comes into contact with intact skin while the absorbent adhesive gel contacts a wound. The additional adhesive provides a dressing with staying power when the absorbent gel has become substantially saturated with wound exudate thus losing some of its adhesiveness through a dilution effect.

A dressing with a polymer or collagen film backing can also be used to anchor to the skin medical devices which are partially inserted into the body such as catheters and tubes. The area where such devices enter the body provide an interface for the entry of bacteria and other infectious agents. The gel of the invention with an appropriate backing, and optimally containing an antimicrobial, is capable of an adhesive effect which keeps the medical device in place while preventing infection at the insertion site. The gel and backing structure can also be punctured with the medical device to provide a more secure entry site.

A gel structure with a polymer film backing is also useful as a burn blanket for serious burns particularly in emergency situations. The wrap can serve the function of cooling the burned area through the heat sink effect of water in the hydrophilic gel, while preventing infection through a barrier effect of a substrate and/or antimicrobial additives incorporated into the gel.

In another embodiment, the gel may be incorporated with a flexible and permeable backing such as a scrim which may be woven or non-woven fabric and which may be stretchable. When medicaments, for example methylsalicylate, nicotinates such as methyl nicotinate, or capsaicin, either alone or in combination, are incorporated into the gel, this structure has particular usefulness as a stretchable sports wrap.

In still another embodiment, the gel may be used in cosmetic preparations such as face masks and nail wraps. The gel serves a hydrating function with or without a backing and a cosmetic effect may be enhanced with the incorporation of other ingredients. A kit for a cosmetic gel may comprise a ready-made gel or two components: a poly(N-vinyl lactam) component and a polyurethane component. Other cosmetic agents such as hydrating agents, fragrances, etc. can also be supplied to the ready-made gel or to either component. For use, the components may be mixed and applied. The gel advantageously can be easily peeled off after use. It shall be understood that the term cosmetic means a preparation intended to enhance or improve physical appearance.

In a further embodiment, fragrances may be incorporated into the gel. When the gel is kept moist in a suitable vented container, the fragrance is slowly released as an air freshener.

The following examples are intended to illustrate but not limit the invention. In the following examples, the K value represents a function of molecular weight. The K value is derived from viscosity measurements and is calculated according to Fikentscher's formula described by Kline, G.M., "Polyvinylpyrrolidone", Modern Plastics p 157 (Nov. 1945) and is also described in General Aniline & Film Corporation Technical Bulletin 7583-033. At the same K-value or molecular weight, the level of ring opened poly(N-vinyl lactam) is an important consideration in determining whether a tacky gel forms.

EXAMPLE 1

A K-92 PVP was titrated with base. The results showed that the PVP had 1.4 mole equivalents/mole of acid groups. Attempts to form a tacky gel using this PVP were unsuccessful. This PVP, when combined with polyurethane, forms a blend which is slippery rather than tacky when formed into a coating or sheet.

EXAMPLE 2

The PVP of Example 1 was heated in water at 60°C for eight days, then at 95°C for eight hours. This material, when titrated with base, showed 2.15 mole equivalents/mole of acid groups and formed a tacky, non-reversible gel at a ratio of 1 PVP/1 urethane at 20% solids.

EXAMPLE 3

A commercial PVP (Kollidon 90, BASF), having a K-value of 93 was titrated with base and showed 5 mole equivalents/mole of acid groups. When mixed with urethane, this PVP formed a hydrophilic, tacky gel.

EXAMPLE 4

A PVP (Luviskol, BASF) having a K-value of 93 was titrated with base and showed less than 1 mole equivalent/mole of acid groups. Attempts to form a gel using this PVP with urethane were unsuccessful. This PVP, when combined with polyurethane, forms a blend which is slippery rather than tacky.

EXAMPLE 5

To a beaker containing 50 grams of a 20% solution of PVP described in Example 3 was added 17.7 grams of distilled water with agitation. When the PVP and water were thoroughly mixed, the agitation was lowered to low shear and NeoRez R-940 water dispersed urethane (Imperial Chemical Industries, Ltd.) was added (32.3 gms at 31% solids). Mixing was continued until the mixture was homogenous. The mixture was then coated onto a polyurethane film with a doctor blade and a silicone coated polyethylene film as a release liner was used to cover the composite. Within 30-60 minutes at room temperature, the tacky gel was not flowable and could be cut to size and packaged in a foil pouch. The gel composition was PVP/polyurethane of 1/1 at 20% solids.

The gel, when put into excess water, absorbed more liquid but did not dissolve or disintegrate. It could be heated, but did not break up even at the boiling point of water.

EXAMPLE 6

To a beaker containing 24 grams of 25% solids aqueous solution of PVP described in Example 3 was added 9.3 grams of distilled water with mechanical agitation. When the PVP was dispersed, 6.7 grams of Sancure 847 (30% solids) (Sanncor Industries), an aliphatic, water-dispersed urethane was added. After mixing so that uniform incorporation occurred, the mixture was cast onto a polypropylene diaper band scrim and doctored to a flat uniform thickness. A polyester film release liner was placed on top of the cast layer to form a composite. This allowed the fabric and tacky gel to stretch to make a well fitting bandage. The gel had a composition of PVP/polyurethane of 3/1 at 20% solids.

EXAMPLE 7

To a beaker containing 50.0 grams of a 20% solution of PVP described in Example 3 with agitation, 16.7 grams of distilled water and 1 gram of silver sulfadiazine were added. When this was thoroughly mixed, 32.3 grams of a water dispersed aromatic urethane NeoRex R-940 were added Slow stirring was continued until mixed, and the mixture was cast on collagen film to which a release film was mated to form a composite. The tacky gel containing 1% silver sulfadiazine can be used as a burn dressing or an antimicrobial interface for a body-inserted medical device.

EXAMPLE 8

To a container was added 60.0 grams of a 20% solution of PVP described in Example 3 and 14.2 grams of distilled water. This was stirred to make a uniform solution. With slow agitation, 25.8 grams of a 31% solution of NeoRez R-940, an aqueous dispersion of an aromatic urethane made from TDI reacted with a dimethylolpropionic acid ethoxylate dispersed by making a salt with triethylamine, was added. Two slabs of gel were made; one on release liner and a second on a thin urethane film by coating a thick layer. The two slabs were allowed to gel at ambient temperature. Then a solution of six grams of salicyclic acid dissolved in 18 ml of ethanol was sprayed onto one slab of the gel and the alcohol allowed to evaporate. The two slabs were then pressed together with a roller to create a gel containing 6% salicyclic acid which can be used for corn removal pads which it an example of a drug delivery system coupled with the advantages of a tacky, hydrophilic gel.

EXAMPLE 9

To a beaker containing 22.7 gm of a 25% solution of PVP described in Example 3, with agitation, 15.0 gm of glycerine and 2.8 g of distilled water were added. When this was thoroughly mixed, 9.5 g of a water dispersed aliphatic urethane Sancure 847 (30% solids) was added. After mixing, it was coated onto a urethane film with an internal nylon scrim to a thickness of about 0.5-0.75 mm. At that point it had a composition of PVP/urethane of 2/1 at 17% solids. The coating was then dryed at 60°C for about 10 minutes. The resultant gel contained about 45-50% of the original weight due to evaporation of water. At this point the gel had substantially stronger tack than before the drying step.

Claims

1. A dressing comprising a stable, tacky, hydrophilic gel which comprises a blend of a polyurethane and a hydrophilic poly(N-vinyl lactam) having a K value of at least 60 and above 1.4 mole equivalents of available acid groups.

2. The dressing of claim 1 which further comprises at least one substrate.

3. The dressing of claim 1 wherein the poly(N-vinyl lactam) comprises polyvinylpyrrolidone homopolymer, copolymer or terpolymer.

4. The dressing of claim 1 wherein the gel comprises a poly(N-vinyl lactam)/polyurethane ratio of from 0.75/1 to about 4/1.

5. The dressing of claim 1 wherein the gel is prepared in an aqueous solution at a total solids of at least 5 weight percent poly(N-vinyl lactam) and polyurethane.

6. The dressing of claim 5 wherein the solution comprises water or a hydroalcohol.

7. The dressing of claim 1 wherein the poly(N-vinyl lactam) has mole equivalents of available acid groups of at least 2.0.

8. The dressing of claim 2 wherein the substrate is selected from a group consisting of polymer film, silicone-polytetrafluorethylene film, collagen film, woven fabric, and non-woven fabric.

9. The dressing of claim 2 wherein the substrate is a polyurethane film.

10. The dressing of claim 2 wherein the substrate is a silicone-polytetrafluoroethylene film.

11. The dressing of claim 2 wherein the substrate is stretchable.

12. The dressing of claim 2 wherein one substrate is a release liner.

13. The dressing of claim 1 wherein the gel comprises at least one additional ingredient.

14. The dressing of claim 13 wherein the additional ingredient is glycerine or propylene glycol.

15. The dressing of claim 13 wherein the additional ingredient is releasable from the gel.

16. The dressing of claim 15 wherein the additional ingredient is a fragrance.

17. The dressing of claim 15 wherein the additional ingredient is a biologically active material.

18. The dressing of claim 17 wherein the additional ingredient is selected from a group consisting of nitroglycerine, scopalamine, pilocarpine, phenylpropanolamine, theophyline, tetracycline, neomycin,

oxytetracycline, triclosan, sodium cefazolin, silver sulfadiazine, salicylates, nicotinates, capsaicin and benzocaine.

19. A method for preparing a stable, tacky, hydrophilic gel dressing comprising mixing an aqueous dispersed poly(N-vinyl lactam) homopolymer or copolymer having a K value of at least 60 and above 1.4 mole equivalents of available acid groups and an aqueous-dispersed polyurethane in a poly(N-vinyl lactam)/polyurethane ratio of from 0.5/1 to 8/1, with a total solids content above 5 weight percent to produce a blend, allowing the blend to cure for a time of from about 10 seconds to about 2 hrs. until a gel dressing is formed.

20. The method of claim 19 which further comprises treating a poly(N-vinyl lactam) to increase mole equivalents of acid groups to above 1.4 by heating the poly(N-vinyl lactam) in aqueous solution at a temperature of from about 50°C to about 200°C, at a pressure of from about 15 psi to about 150 psi, for about one-half hour to about 10 days.

21. The method of claim 20 wherein the aqueous solution has a pH of from 7 to about 9.

22. The method of claim 19 which further comprises adding a biologically active material to the blend.

23. The method of claim 22 wherein the biologically active material is an antimicrobial agent.

24. The method of claim 19 wherein the blend is formed into a dressing by coating or casting the blend onto a substrate.

25. The method of claim 24 wherein the blend is covered with a second substrate which is a release liner.

26. The method of claim 19 wherein the blend is formed into a dressing by casting two separate slabs of gel onto two separate substrates, applying a solution of a biologically active material to a surface of one of the slabs, and compressing the slabs together so that the biologically active material is located between the slabs.

27. The method of claim 26 wherein the biologically active material is selected from the group consisting of salicylates, nicotinates and capsaicin.

28. The dressing of claim 1 in the form of a product selected from a group consisting of wound dressings, burn dressings, drug delivery dressings, antimicrobial interface dressings for anchoring medical devices to the skin, sports wrap dressings, cosmetic mask dressings and cosmetic wrap dressings.

29. A stable, tacky, hydrophilic gel which comprises a blend of polyurethane and a hydrophilic poly(N-vinyl lactam) having a K value of at least 60 and above 1.4 mole equivalents of available acid groups, the polyurethane and poly(N-vinyl lactam) combined in a polyurethane/poly(N-vinyl lactam) ratio from 0.5/1 to 8/1 in an aqueous solution at a total solids of at least five weight percent.

Patentansprüche

1. Ein Wundverband, umfassend ein stabiles, klebriges, hydrophiles Gel, das ein Gemisch aus einem Polyurethan und einem hydrophilen Poly(N-vinyllactam) mit einem K-Wert von mindestens 60 und mehr als 1,4 Moläquivalenten verfügbarer saurer Gruppen umfaßt.

2. Der Wundverband aus Anspruch 1, der darüber hinaus mindestens einen Träger umfaßt.

3. Der Wundverband aus Anspruch 1, wobei das Poly(N-vinyllactam) Polyvinylpyrrolidon-Homopolymer, -Copolymer oder -Terpolymer umfaßt.

4. Der Wundverband aus Anspruch 1, wobei das Gel ein Poly(N-vinyllactam)/Polyurethan-Verhältnis von 0,75/1 bis etwa 4/1 umfaßt.

5. Der Wundverband aus Anspruch 1, wobei das Gel in einer wäßrigen Lösung mit einem Gesamtfeststoffgehalt von mindestens 5 Gew.-% Poly(N-vinyllactam) und Polyurethan hergestellt wird.

6. Der Wundverband aus Anspruch 5, wobei die Lösung Wasser oder einen Hydroalkohol umfaßt.

7. Der Wundverband aus Anspruch 1, wobei das Poly(N-vinyllactam) mindestens 2,0 Moläquivalente saure Gruppen aufweist.

8. Der Wundverband aus Anspruch 2, wobei der Träger ausgewählt wird aus einer aus Polymerfilm, Silicon-Polytetrafluorethylenfilm, Collagenfilm, Gewebe und Faservlies bestehenden Gruppe.

9. Der Wundverband aus Anspruch 2, wobei das Substrat ein Polyurethanfilm ist.

10. Der Wundverband aus Anspruch 2, wobei das Substrat ein Silicon-Polytetrafluorethylenfilm ist.

11. Der Wundverband aus Anspruch 2, wobei das Substrat dehnbar ist.

12. Der Wundverband aus Anspruch 2, wobei ein Substrat ein entfernbarer Schutzüberzug ist.

13. Der Wundverband aus Anspruch 1, wobei das Gel mindestens einen zusätzlichen Bestandteil umfaßt.

14. Der Wundverband aus Anspruch 13, wobei der zusätzliche Bestandteil Glycerin oder Propylenglycol ist.

15. Der Wundverband aus Anspruch 13, wobei der zusätzliche Bestandteil aus dem Gel freigesetzt werden kann.

16. Der Wundverband aus Anspruch 15, wobei der zusätzliche Bestandteil ein Duftstoff ist.

17. Der Wundverband aus Anspruch 15, wobei der zusätzliche Bestandteil ein biologisch aktives Material ist.

18. Der Wundverband aus Anspruch 17, wobei der zusätzliche Bestandteil ausgewählt wird aus einer aus Nitroglycerin, Scopalamin, Pilocarpin, Phenylpropanolamin, Theophyllin, Tetracyclin, Neomycin, Oxytetracyclin, Triclosan, Natriumcefazolin, Silbersulfadiazin, Salicylaten, Nicotinaten, Capsaicin und Benzocain bestehenden Gruppe.

19. Ein Verfahren zur Herstellung eines stabilen, klebrigen, hydrophilen Gel-Wundverbands, umfassend Mischen eines wäßrigen dispergierten Poly(N-vinyllactam)-Homopolmeren oder -Copolymeren mit einem K-Wert von mindestens 60 und mehr als 1,4 Moläquivalenten verfügbarer Säuregruppen und eines wäßrig dispergierten Polyurethans in einem Poly(N-vinyllactam)/Polyurethan-Verhältnis von 0,5/1 bis 8/1 mit einem Gesamtfeststoffgehalt von mehr als 5 Gew.-% zur Herstellung einer Mischung und Härten der Mischung während einer Zeit von etwa 10 Sekunden bis etwa 2 Stunden, bis ein Gel-Wundverband gebildet ist.

20. Das Verfahren des Anspruchs 19, das darüber hinaus Behandeln eines Poly(N-vinyllactam) zur Erhöhung der Moläquivalente freier saurer Gruppen auf mehr als 1,4 durch Erhitzen des Poly(N-vinyllactam) in wäßriger Lösung bei einer Temperatur von etwa 50°C bis etwa 200°C bei einem Druck von etwa 15 psi bis etwa 150 psi während etwa einer halben Stunde bis etwa 10 Tagen umfaßt.

21. Das Verfahren aus Anspruch 20, wobei die wäßrige Lösung einen pH von 7 bis 9 aufweist.

22. Das Verfahren aus Anspruch 19, das darüber hinaus Zugabe eines biologisch aktiven Materials zu der Mischung umfaßt.

23. Das Verfahren aus Anspruch 22, wobei das biologisch aktive Material ein antimikrobielles Mittel ist.

24. Das Verfahren aus Anspruch 19, wobei die Mischung durch Auftragen oder Gießen der Mischung auf einen Träger zu einem Wundverband geformt wird.

25. Das Verfahren aus Anspruch 24, wobei die Mischung mit einem zweiten Träger bedeckt wird, der ein entfernbarer Schutzüberzug ist.

26. Das Verfahren aus Anspruch 19, wobei die Mischung durch Gießen zweier getrennter Tafeln aus Gel auf zwei getrennte Träger, Auftragen einer Lösung eines biologisch aktiven Materials auf die Oberfläche einer der Tafeln, und Zusammenpressen beider Tafeln zu einem Wundverband geformt wird, so daß das biologisch aktive Material zwischen beiden Tafeln angeordnet ist.

27. Das Verfahren aus Anspruch 26, wobei das biologisch aktive Material ausgewählt wird aus der aus Salicylaten, Nicotinaten und Capsaicin bestehenden Gruppe.

28. Der Wundverband aus Anspruch 1, in der Form eines Produkts, ausgewählt aus einer aus Wundverbänden, Brandverbänden, Arzneimittelfreisetzungsverbänden, antimikrobiellen Zwischenverbänden für die Anbringung medizinischer Geräte auf der Haut, Sportbandagen, kosmetischen Masken und kosmetischen Bandagen bestehenden Gruppe.

29. Ein stabiles, klebriges, hydrophiles Gel, das eine Mischung aus Polyurethan und einem hydrophilen Poly(N-vinyllactam) mit einem K-Wert von mindestens 60 und mehr als 1,4 Moläquivalenten verfügbarer Säuregruppen umfaßt, wobei das Polyurethan und das Poly(N-vinyllactam) in einem Polyurethan/Poly(N-vinyllactam)-Verhältnis von 0,5/1 bis 8/1 in wäßriger Lösung mit einem Gesamtfeststoffgehalt von mindestens 5 Gew.-% kombiniert sind.

Revendications

1. Pansement comprenant un gel hydrophile, collant et stable, qui est constitué d'un mélange d'un polyuréthane et d'un poly(N-vinyl-lactame) hydrophile ayant une valeur K d'au moins 60 et plus de 1,4 équivalent molaire de groupes acides disponibles.

2. Pansement selon la revendication 1, comprenant, en outre, au moins un substrat.

3. Pansement selon la revendication 1, dans lequel le poly(N-vinyl-lactame) comprend un homopolymère, un copolymère ou un terpolymère de polyvinylpyrrolidone.

4. Pansement selon la revendication 1, dans lequel le gel présente un rapport de poly(N-vinyl-lactame)/polyuréthane compris entre 0,75/1 et environ 4/1.

5. Pansement selon la revendication 1, dont le gel est préparé dans une solution aqueuse avec une teneur totale en solides d'au moins 5 % en poids de poly(N-vinyl-lactame) et de polyuréthane.

6. Pansement selon la revendication 5, la solution étant constituée d'eau ou d'un hydroalcool.

7. Pansement selon la revendication 1, dans lequel le poly(N-vinyl-lactame) a un équivalent molaire de groupes acides disponibles d'au moins 2,0.

8. Pansement selon la revendication 2, le substrat étant choisi dans l'ensemble constitué par un film polymère, un film de silicone-polytétrafluoroéthylène, un film de collagène, un tissu et un non-tissé.

9. Pansement selon la revendication 2, dans lequel le substrat est un film de polyuréthane.

10. Pansement selon la revendication 2, dans lequel le substrat est un film de silicone-polytétrafluoroéthylène.

11. Pansement selon la revendication 2, dans lequel le substrat est étirable.

12. Pansement selon la revendication 2, dans lequel un substrat est un papier de séparation.

13. Pansement selon la revendication 1, dans lequel le gel comprend au moins un ingrédient supplémentaire.

14. Pansement selon la revendication 13, dans lequel l'ingrédient supplémentaire est le glycérol ou un propylèneglycol.

15. Pansement selon la revendication 13, dans lequel l'ingrédient supplémentaire est séparable du gel.

16. Pansement selon la revendication 15, dans lequel l'ingrédient supplémentaire est un parfum.

17. Pansement selon la revendication 15, dans lequel l'ingrédient supplémentaire est une substance biologiquement active.

18. Pansement selon la revendication 17, dans lequel l'ingrédient supplémentaire est choisi dans l'ensemble constitué par la nitroglycérine, la scopalamine, la pilocarpine, la phénylpropanolamine, la théophylline, la tétracycline, la néomycine, l'oxytétracycline, le triclosan, la céfazoline sodique, la sulfadiazine argentique, les salicylates, les nicotinates, la capsaïcine et la benzocaïne.

19. Procédé de préparation d'un pansement à base de gel hydrophile, collant et stable, comprenant les étapes consistant à mélanger une solution aqueuse d'un homopolymère ou d'un copolymère de poly(N-vinyl-lactame) dispersé, ayant une valeur K d'au moins 60 et plus de 1,4 équivalent molaire de groupes acides disponibles, avec une solution aqueuse d'un polyuréthane dispersé, à un rapport de poly(N-vinyl-lactame)/polyuréthane de 0,5/1 à 8/1, avec une teneur totale en solides supérieure à 5 % en poids, de façon à produire un mélange, laisser durcir ce mélange pendant un laps de temps d'environ 10 secondes à environ 2 heures, jusqu'à ce qu'un pansement à base de gel soit formé.

20. Procédé selon la revendication 19, comprenant, en outre, le traitement d'un poly(N-vinyl-lactame) de façon à augmenter le nombre d'équivalents molaires de groupes acides au-delà de 1,4 en chauffant le poly(N-vinyl-lactame) en solution aqueuse à une température comprise entre environ 50°C et environ 200°C, à une pression d'environ 15 psi à environ 150 psi, pendant environ une demi-heure à environ 10 jours.

21. Procédé selon la revendication 20, dans lequel la solution aqueuse a un pH compris entre 7 et environ 9.

22. Procédé selon la revendication 19, comprenant, en outre, l'addition d'une substance biologiquement active au mélange.

23. Procédé selon la revendication 22, dans lequel la substance biologiquement active est un agent antimicrobien.

24. Procédé selon la revendication 19, dans lequel on transforme le mélange en un pansement en appliquant ou en coulant le mélange sur un substrat.

25. Procédé selon la revendication 24, dans lequel on recouvre le mélange d'un deuxième substrat qui est un papier de séparation.

26. Procédé selon la revendication 19, dans lequel on transforme le mélange en un pansement en coulant deux plaques séparées de gel sur deux substrat séparés, appliquant une solution d'une substance biologiquement active sur une surface d'une des plaques, et comprimant les plaques ensemble de telle sorte que la substance biologiquement active soit située entre les plaques.

27. Procédé selon la revendication 26, dans lequel la substance biologiquement active est choisie dans

l'ensemble constitué par les salicylates, les nicotinates et la capsaïcine.

28. Pansement selon la revendication 1 sous la forme d'un produit choisi dans l'ensemble constitué par les pansements pour blessures, les pansements pour brûlures, les pansements libérant un médicament, les pansements antimicrobiens d'interface pour fixer des dispositifs médicaux sur la peau, des pansements enveloppants pour la pratique d'un sport, des pansements du type masque cosmétique et des pansements cosmétiques enveloppants.

29. Gel hydrophile, collant et stable, comprenant un mélange de polyuréthane et d'un poly(N-vinyl-lactame) hydrophile, ayant une valeur K d'au moins 60 et plus de 1,4 équivalent molaire de groupes acides disponibles, le polyuréthane et le poly(N-vinyl-lactame) étant combinés d'une manière telle que le rapport du polyuréthane au poly(N-vinyl-lactame) est compris entre 0,5/1 et 8/1, en solution aqueuse ayant une teneur totale en solides d'au moins 5 % en poids.